California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Daze, Board Member
Hank Hough, Board Member
Ken Schell, PharmD, Board Vice President

LEGISLATIVE REPORT AND ACTION

1. Board-Sponsored Legislation

- **SB 1476 (Figueroa) Board Sunset Extension Bill**
  Status: Chaptered

  This bill extends the board's sunset date for two years, from 2008 to 2010. The board's sunset report will be due to the Legislature in September 2008. The bill also extends a report on those who fail the pharmacist licensure examination four times and must take remedial education until 2008.

  In addition this legislation delays the implementation date for electronic pedigree requirements on prescription medicine sold in California from January 2007 to January 1, 2009. The bill also allows the board to extend implementation until 2011 if the board believes the technology is not yet ready.

  Additional provisions exclude drug samples from e-pedigree requirements and exclude until 2010 injectable medicines that are not dispensed to patients, but administered by providers directly to patients. The electronic pedigree system must be interoperable through all distribution levels, serialized to the product container level, and drugs returned to wholesalers must retain the initiating pedigree. The board must be notified about suspected or actual counterfeiting and repackagers must continue the pedigree through repackaging operations.

  The board's Enforcement Committee continues quarterly meetings with manufacturers and wholesalers to monitor the implementation progress of the electronic pedigree requirement.

Attachment 1 contains the bill and a Power Point presentation prepared by Supervising Inspector Nurse detailing SB 1476's pedigree requirements.

- **SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill**
  Status: Chaptered

  This bill:
  1. Allows a check-off box on electronic prescriptions that, if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion.
  2. Clarifies requirements for reporting to the board when a license is impaired to the extent it affects the licensee's safe practice or the licensee has stolen or diverted drugs.
  3. Establishes the authority to issue a temporary sterile injectable compounding license following a change of ownership
  4. Exempts government-owned wholesalers from having to post a $100,000 bond.
  5. Exempts drug manufacturers who hold a biologics license application form the FDA from having to post a $100,000 bond.
  6. Makes technical and conforming changes in the licensure requirements for clinics.

  Attachment 2 contains this bill.

- **AB 2408 (Negrete McLeod) Pharmacists, pharmacies and nonresident pharmacies**
  Status: Chaptered

  This bill reorganizes the pharmacist protocol provisions in Business and Professions Code section 4052 into four more readable sections. The bill also:
  -- specifically states that the practice of a pharmacist occurs within and outside a pharmacy.
  -- adds a statement that "pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities."

  There are several other changes made in disciplinary provisions regarding nonresident pharmacies.

  The bill formerly contained provisions important to the board that were vigorously opposed by the California Medical Association. These provisions were amended out of the bill in late August. The provisions removed would have identified three primary types of pharmacies, although any pharmacy could do all three functions (dispensing, prescription processing, advice/clinical center).

The bill also contained a list of professional duties that pharmacists typically perform (for which they educated and which are tested on the NAPLEX and CPJE exams) that are not listed in law. Provisions describing the functions pharmacists perform were

-- interpreting, verifying and implementing drug orders and prescriptions
-- dispensing pursuant to legitimate drug orders and prescriptions
-- ensuring proper drug storage, documentation, inventory, labeling and recordkeeping
-- maintaining accurate, complete and confidential patient profiles and records
-- supervising pharmacy technicians and other ancillary personnel in the pharmacy
-- designing and implementing quality assurance procedures and protocols
-- compounding drug products pursuant to prescription and for prescriber office use
-- maintaining safe, secure and sanitary conditions in licensed premises
-- collaborating with prescribers and other health care providers regarding patient care
-- implementing standardized procedures and protocols regarding patient care
-- administering or furnishing drugs or biologicals where permitted by law
-- initiating, adjusting or implementing patient drug regimens as authorized by law
-- performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation

It was the last provision that drew CMA's opposition.

If the board determines to pursue this legislation in the future, we need to lay some preparation with all pharmacy associations and then work with CMA to resolve the issues before reintroducing the bill.

Attachment 3 contains this bill.

- **AB 595 (Negrete McLeod) Pharmacy: compounding of prescription drugs.**
  Status: Withdrawn by Board

This bill would have established standards for pharmacies that compound medications pursuant to a prescription or via contract with another pharmacy. In 2004, the Licensing Committee formed a Workgroup on Compounding to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. This workgroup formed in part due to a request from the Department of Health Services seeking the board's

determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or FDA the determination of when a pharmacy is manufacturing.

The board sponsored the proposed statutory provisions in this bill. In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but we were never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

And at the very end of the 2006 legislative session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing DHS' opposition. However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments, although former Executive Officer Patricia Harris feels that these amendments had been agreed upon earlier, the bill was dropped at the end of the session (DHS never removed its opposition).

2. Enacted Legislation Related to the Practice of Pharmacy

- **AB 225 (Negrete McLeod) Electronic prescription information**
  Status: Chaptered

  This bill aligns state law with federal law allowing healthcare facilities to receive nonmonetary goods and services (e.g., palm pilots) for the purposes of transmitting prescription information electronically without violating the kickback provisions contained in Business and Professions Code section 650.

- **AB 2198 (Houston) Health care: controlled substances and dangerous drugs**
  Status: Chaptered

  This legislation revises and recasts existing law relating to the prescribing or administration of drugs for the treatment or management of pain in the Medical

Practices Act, and provides that physicians who have a medical basis for prescribing or administering dangerous drugs or controlled substances shall not be subject to disciplinary action or prosecution under specified circumstances. It also revises the provisions relating to physicians who prescribe, dispense or administer a controlled substance to an addict or habitual user and broadens the Intractable Pain Treatment Act to allow physician's to prescribe or administer certain drugs for the treatment of pain or a condition causing pain, including but not limited to, intractable pain.

- **AB 2373 (Plescia) Automated drug delivery system**
  Status: Chaptered

  This bill expands the use of automated drug delivery systems (ADDS) in nursing facilities and makes other changes related to the stocking of ADDS. In addition, it exempts drugs dispensed from an ADDS machine from existing law labeling requirements if the drugs are in blister pack cards.

- **AB 2583 (Nation) Dispensing prescription drugs and devices: refusal to dispense**
  Status: Chaptered

  This bill requires the board's Notice to Consumers to be revised to contain a statement describing patients' rights to prescription drugs or devices, and to inform patients of their right to timely access to prescribed drugs and devices even if a licentiate refuses to dispense a drug or device based on ethical, moral, or religious grounds.

  The board must promulgate a regulation to make this change. Board staff developed the regulatory language required to implement this legislative change, which was discussed under the Communication and Public Education Committee report at this meeting.

- **AB 2877 (Frommer) Prescription drugs: importation: procurement**
  Status: Chaptered

  This legislation requires the Department of Health Services (DHS) to establish a Web site to facilitate purchasing prescription drugs at reduced prices and requires that the Web site include price comparisons of at least 150 commonly prescribed prescription drugs, including typical prices charged by pharmacies in the state. In addition, it requires the Department of General Services (DGS) to report to the Legislature on specified activities related to the procurement of prescription drugs.

- **AB 2911 (Nunez) California Discount Prescription Drug Program**
  Status: Chaptered

This bill establishes the California Discount Prescription Drug Program (Program) in the Department of Health Services (DHS) to use manufacturer rebates and pharmacy discounts in order to reduce prescription drug prices and improve the quality of health care for eligible Californians.

- **AB 2986 (Mullin) Controlled substances: prescription requirements**
  Status: Chaptered

  This bill brings California law into conformance with the federal National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 by including Schedule IV controlled substances within the CURES (Controlled Substances Utilization Review and Evaluation System) system. Beginning January 1, 2007, Schedule IV medications dispensed in California by pharmacies and prescribers must be reported to CURES.

  The bill requires pharmacies and prescribers dispensing controlled drugs to submit CURES data weekly. The bill also adds new items into the patient's data field in CURES, such as a telephone number.

  This is an important bill to pharmacies' operations that will require pharmacies potentially to modify their software programs to comply with the requirements. The board is developing a fact sheet for pharmacies on this bill.

- **AJR 40 (Chan) Medicare Prescription Drugs**
  Status: Chaptered

  This measure memorializes the United States Congress and President to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005."

- **ARJ 49 (Nation) Direct-To-Consumer Prescription Drug Advertisements**
  Status: Chaptered

  This resolution requests that the United States Food and Drug Administration aggressively monitor and regulate direct-to-consumer television advertising of prescription drugs by pharmaceutical companies and memorializes the President and the Congress of the United States to ban television advertising of prescription drugs.

- **SB 1305 (Figueroa) The Medical Waste Management Act**
  Status: Chaptered

  This legislation prohibits a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

- **SB 1430 (Alquist) The Local Pandemic and Emergency Health Preparedness Act of 2006**
  Status: Chaptered

  This bill permits the director of the Department of Health Services to declare a health emergency and the local health officer to declare a local health emergency in the jurisdiction in specified instances. The bill permits a local health officer to issue an order to first responders for the purpose of immediately isolating exposed individuals in specified instances and with specified limitations.

4. Legislation related to the Practice of Pharmacy that Failed Passage

AB 2308 (Plescia) Ambulatory surgical centers: licensure.
Status: Vetoed
The veto message is provided in **Attachment 4**.

AB 21 (Levine) Pharmacists: contraceptive devices
Status: Failed Passage

AB 71 (Chan) Pharmaceuticals: adverse drug reactions: Office of CA Drug Safety Watch
Status: Failed Passage

AB 75 (Frommer) Pharmaceutical assistance program
Status: Failed Passage

AB 283 (Koretz) Pseudoephedrine: retail sale.
Status: Failed Passage

AB 651 (Berg) California Compassionate Choices Act
Status: Failed Passage

AB 657 (Karnette) Pharmacies: prescription containers
Status: Failed Passage

AB 1908 (Karnette) Medi-Cal: pharmacy reimbursement
Status: Failed Passage

AB 2057 (Cogdill) Controlled substances.
Status: Failed Passage

AB 2730 (Nation) Medi-Cal: contract drug list: advertising.
Status: Failed Passage

AB 2743 (Matthews) Pharmacists: ancillary personnel.

Status: Failed Passage

AB 2856 (Hancock) Informed consent: prescription medication off-label use.
Status: Failed Passage

SB 380 (Alquist) Drugs: adverse event reporting
Status: Failed Passage

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.
Status: Failed Passage

SB 1366 (Aanestad) Controlled substances.
Status: Failed Passage

SB 1683 (Scott) Pharmaceutical information: clinical trial data.
Status: Died in Senate

Attachment 1

Senate Bill 1476

Senate Bill No. 1476

CHAPTER 658

An act to amend Sections 30, 101, 205, 473.15, 1601.1, 1616.5, 1742, 1770, 2460, 2570.4, 2570.19, 2602, 2668, 2701, 2708, 2920, 2933, 3010.5, 3014.6, 3504, 3512, 3516.1, 3685, 3710, 3716, 3765, 4001, 4003, 4034, 4162, 4162.5, 4163.5, 4169, 4200.1, 4800, 4804.5, 4928, 4934, 5510, 5517, 5620, 5621, 5622, 5810, 5811, 6704, 6710, 6712, 6714, 6716, 6726.2, 6730, 6732.3, 6738, 6740, 6750, 6753, 6754, 6787, 7000.5, 7011, 7200, 7215.6, 7810, 7815.5, 8000, 8710, 8729, 8740, 8745, and 22251 of, to amend and repeal Sections 1760, 1760.5, 1761, 1762, 1763, 1764, 1765, 1766, 1768, 1769, 1772, 1774, 1775, and 4163 of, to amend, repeal, and add Sections 1621, 1670.1, 1680, 1721, 1721.5, 1741, 1742.1, 1743, 1744, 1771, 4999.2, and 4999.7 of, to add Sections 1900.5, 2660.5, 4163.1, 6732.5, and 6746.1 to, and to repeal Section 4163.6 of, the Business and Professions Code, to amend, repeal, and add Section 44876 of the Education Code, and to amend, repeal, and add Sections 1348.8 and 128160 of the Health and Safety Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1476, Figueroa. Professions and vocations.

(1) Existing law regulates various professions and vocations by various boards within the Department of Consumer Affairs. Existing law requires those boards, and the State Bar of California and the Department of Real Estate, to require a licensee, at the time of issuance or renewal of a license, to provide the licensee's federal employer identification number, if the licensee is a partnership, or his or her social security number.

This bill would instead impose that requirement only when a license is issued.

(2) Existing law provides for the licensing and regulation of dentists by the Dental Board of California, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would make nonsubstantive changes to those provisions.

(3) Existing law provides for the licensing and regulation of dental auxiliaries by the Committee on Dental Auxiliaries, and makes those provisions inoperative on July 1, 2008, and repeals them on January 1, 2009.

This bill would instead make those provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010, if SB 1472 is not enacted.

If SB 1472 is enacted and becomes effective on or before January 1, 2007, it would, among other things, rename the Committee on Dental Auxiliaries the Committee on Dental Assistants and revise the membership of the committee, and would create the California Dental Hygiene Bureau in the Department of Consumer Affairs and the Dental Hygiene Advisory Committee in the bureau.

This bill would make those provisions operative on January 1, 2008, instead of January 1, 2007, and would make other conforming changes, if SB 1472 is enacted.

(4) Existing law provides for the licensure and regulation of psychologists by the Board of Psychology, requires the board to employ necessary personnel, and authorizes the board to employ an executive officer. Existing law provides for the licensure and regulation of acupuncturists by the Acupuncture Board and requires the board to employ necessary personnel, including an executive officer. Existing law provides for the licensure and regulation of geologists and geophysicists by the Board for Geologists and Geophysicists and for the licensure and regulation of court reporters by the Court Reporters Board of California. Existing law provides for the licensure and regulation of contractors by the Contractors' License Board. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(5) Existing law provides for the licensing and regulation of podiatrists by the California Board of Podiatric Medicine, within the jurisdiction of the Medical Board of California. Existing law provides for the licensure and regulation of registered nurses by the Board of Registered Nursing, in the Department of Consumer Affairs, and requires the board to appoint an executive officer. Existing law provides for the licensure and regulation of optometrists by the State Board of Optometry, in the Department of Consumer Affairs, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

(6) Existing law, the Occupational Therapy Practice Act, provides for the licensing and regulation of occupational therapists and the certification and regulation of occupational therapy assistants by the California Board of Occupational Therapy. These provisions will become inoperative on July 1, 2007, and will be repealed on January 1, 2008.

This bill would instead make these provisions inoperative on July 1, 2013, and would repeal them on January 1, 2014.

Existing law exempts certain persons from the requirements of the act, including a licensee from a state with commensurately stringent

This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 59. Section 3716 of the Business and Professions Code is amended to read:

3716. The board may employ an executive officer exempt from civil service and, subject to the provisions of law relating to civil service, clerical assistants and, except as provided in Section 159.5, other employees as it may deem necessary to carry out its powers and duties.

This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 60. Section 3765 of the Business and Professions Code is amended to read:

3765. This act does not prohibit any of the following activities:

(a) The performance of respiratory care that is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.

(b) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.

(c) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.

(d) The performance of respiratory care in an emergency situation by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their speciality.

(e) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.

(f) Persons from engaging in cardiopulmonary research.

(g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Health Services of specific, limited, and basic respiratory care or respiratory care related services that have been authorized by the board.

SEC. 61. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 62. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 63. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and

distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are not required to be recorded on a pedigree:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.

SEC. 64. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

SEC. 65. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of

any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2015, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends those dates.

SEC. 66. Section 4163 of the Business and Professions Code, as amended by Section 31 of Chapter 857 of the Statutes of 2004, is repealed.

SEC. 67. Section 4163 of the Business and Professions Code, as added by Section 32 of Chapter 857 of the Statutes of 2004, is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

SEC. 68. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

SEC. 69. Section 4163.5 of the Business and Professions Code is amended to read:

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163 until January 1, 2011, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 70. Section 4163.6 of the Business and Professions Code is repealed.

SEC. 71. Section 4169 of the Business and Professions Code, as added by Section 39 of Chapter 857 of the Statutes of 2004, is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

SEC. 72. Section 4169 of the Business and Professions Code, as added by Section 40 of Chapter 857 of the Statutes of 2004, is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall become operative on January 1, 2008.

SEC. 73. Section 4200.1 of the Business and Professions Code is amended to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

SEC. 74. Section 4800 of the Business and Professions Code is amended to read:

4800. There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of seven members, three of whom shall be public members.

This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.

The repeal of this section renders the board subject to the review provided for by Division 1.2 (commencing with Section 473).

SEC. 75. Section 4804.5 of the Business and Professions Code is amended to read:

4804.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes

Attachment 2

SB 1475

Senate Bill No. 1475

CHAPTER 659

An act to amend Sections 725, 800, 1646.9, 2079, 2533, 4073, 4104, 4162, 4162.5, 4180, 4181, 4182, 4190, 4191, 4192, 4546, 4548, 4994, 4996.17, 4999, 4999.1, and 4999.4 of, to amend the heading of Article 4 (commencing with Section 4996) of Chapter 14 of Division 2 of, to add Chapter 13.5 (commencing with Section 4989.10) and Chapter 13.7 (commencing with Section 4990) to Division 2 of, to add Sections 4127.8, 4991, and 4991.2 to, to repeal Article 5 (commencing with Section 4986) of Chapter 13 and Article 1 (commencing with Section 4990) of Chapter 14 of Division 2 of, and to repeal Sections 4992.31, 4998.6, 4999.8, and 4999.9 of, the Business and Professions Code, relating to the healing arts, and making an appropriation therefor.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1475, Committee on Business, Professions and Economic Development. Healing arts.

(1) Existing law makes repeated acts of clearly excessive prescribing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist. Existing law also requires various healing arts boards to separately create and maintain a central file, to provide an individual historical record for each licensee, of the names of all persons who hold a license, certificate, or similar authority from that board.

The bill would also make these provisions applicable to, respectively, speech-language pathologists and audiologists and the Speech-Language Pathology and Audiology Board.

(2) Existing law creates the Board of Behavioral Sciences and makes it responsible for the licensure and regulation of clinical social workers and educational psychologists. Under existing law, moneys received by the board are deposited into the Behavioral Sciences Fund and are continuously appropriated to the board, other than the revenue from fines and penalties. Existing law makes a violation of the provisions regulating these practitioners a crime.

This bill would recast the provisions creating the board. The bill would name provisions regulating social workers the Clinical Social Worker Practice Act and would modify licensure requirements with respect to experience gained outside this state. The bill would also establish the

SEC. 6. Section 4073 of the Business and Professions Code is amended to read:

4073. (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

SEC. 7. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or

with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

SEC. 8. Section 4127.8 is added to the Business and Professions Code, to read:

4127.8. The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred dollars ($500) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested at the licenseholder's address of record with the board,

whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

SEC. 9. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant, that is not a government-owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 10. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 11. Section 4180 of the Business and Professions Code is amended to read:

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (*l*) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

SEC. 12. Section 4181 of the Business and Professions Code is amended to read:

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 13. Section 4182 of the Business and Professions Code is amended to read:

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

SEC. 14. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

SEC. 14.5. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) Notwithstanding any provision of this chapter, an ambulatory surgical center, licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, accredited by an accreditation agency pursuant to Section 1248 of the Health and Safety Code, or certified to participate in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the center, as provided in subdivision (b). The center shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) The drug distribution service of an ambulatory surgical center shall be limited to the use of drugs for administration to the patients of the ambulatory surgical center and to the dispensing of drugs for the control of pain and nausea for patients of the center. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No ambulatory surgical center shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each center location. A center shall notify the board of any change in the center's address on a form furnished by the board.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

SEC. 15. Section 4191 of the Business and Professions Code is amended to read:

4191. (a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 16. Section 4192 of the Business and Professions Code is amended to read:

4192. (a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the

application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

SEC. 17. Section 4546 of the Business and Professions Code is amended to read:

4546. The board shall report each month to the Controller the amount and source of all revenue received by it pursuant to this chapter and at the same time pay the entire amount thereof into the State Treasury for credit to the Vocational Nursing and Psychiatric Technicians Fund.

SEC. 18. Section 4548 of the Business and Professions Code is amended to read:

4548. The amount of the fees prescribed by this chapter in connection with the issuance of licenses under its provisions shall be according to the following schedule:

(a) The fee to be paid upon the filing of an application shall be in an amount not less than one hundred dollars ($100), and may be fixed by the board at an amount no more than one hundred fifty dollars ($150).

(b) The fee to be paid for taking each examination shall be the actual cost to purchase an examination from a vendor approved by the board.

(c) The fee to be paid for any examination after the first shall be in an amount of not less than one hundred dollars ($100), and may be fixed by the board at an amount no more than one hundred fifty dollars ($150).

(d) The biennial renewal fee to be paid upon the filing of an application for renewal shall be in an amount not less than two hundred dollars ($200), and may be fixed by the board at an amount no more than three hundred dollars ($300).

(e) Notwithstanding Section 163.5, the delinquency fee for failure to pay the biennial renewal fee within the prescribed time shall be in an amount not less than one hundred dollars ($100) and may be fixed by the board at not more than 50 percent of the regular renewal fee and in no case more than one hundred fifty dollars ($150).

(f) The initial license fee is an amount equal to the biennial renewal fee in effect on the date the application for the license is filed.

(g) The fee to be paid for an interim permit shall be in an amount no less than twenty dollars ($20) and may be fixed by the board at an amount no more than fifty dollars ($50).

Attachment 3

AB 2408

Assembly Bill No. 2408

CHAPTER 777

An act to amend Sections 4036, 4050, 4052, 4301, and 4306.5 of, to amend, renumber, and add Section 4052.1 of, to add Sections 4052.2 and 4052.3 to, and to repeal and add Section 4303 of, the Business and Professions Code, relating to pharmacies.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2408, Negrete McLeod. Pharmacies.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacies by the Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime.

Existing law defines a pharmacist and a pharmacy, requires pharmacists and pharmacies to be licensed by the board, and authorizes a licensee to engage in certain activities. Existing law also sets forth activities that constitute unprofessional conduct for a pharmacist to engage in.

This bill would require a pharmacist to be a natural person, and would entitle a licensed pharmacist to practice pharmacy within or outside of a licensed pharmacy. The bill would revise the activities in which a pharmacist may engage, including the adjustment of prescriptions, would revise the pharmacist's responsibilities and requirements with regard to certain activities, and would make certain additional acts or omissions unprofessional conduct.

Existing law defines a nonresident pharmacy and requires a nonresident pharmacy to meet certain criteria, including registration with the board. Existing law authorizes the board to deny, revoke, or suspend a nonresident registration for failure to comply with specified requirements or for conduct that causes serious bodily or psychological injury to a California resident, in specified circumstances.

This bill would delete the authorization for the board to deny, revoke, or suspend a nonresident registration for failure to comply with specified requirements or for conduct causing serious bodily harm or psychological injury to a California resident, and would instead authorize the board to deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment, or take any other action against a nonresident pharmacy that it may take against a resident pharmacy on any of the same grounds upon which the action might be taken against a resident pharmacy, if action may be taken against the nonresident pharmacy in its own state for the conduct. The bill would also authorize

the board to report violations of laws or regulations by a nonresident pharmacy to any appropriate state or federal regulatory or licensing agency.

This bill would revise and recast related provisions of the Pharmacy Law.

Because this bill would create new requirements and prohibitions under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4036 of the Business and Professions Code is amended to read:

4036. "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

SEC. 2. Section 4050 of the Business and Professions Code is amended to read:

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

SEC. 3. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

(9) Administer immunizations pursuant to a protocol with a prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 4. Section 4052.1 of the Business and Professions Code is amended and renumbered to read:

4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 5. Section 4052.1 is added to the Business and Professions Code, to read:

4052.1. (a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

SEC. 6. Section 4052.2 is added to the Business and Professions Code, to read:

4052.2. (a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

SEC. 7. Section 4052.3 is added to the Business and Professions Code, to read:

4052.3. (a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total

retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 8. Section 4301 of the Business and Professions Code, as added by Section 44 of Chapter 857 of the Statutes of 2004, is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type

and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with

Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006.

SEC. 9. Section 4303 of the Business and Professions Code is repealed.

SEC. 10. Section 4303 is added to the Business and Professions Code, to read:

4303. (a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

(b) The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

SEC. 11. Section 4306.5 of the Business and Professions Code is amended to read:

4306.5. Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

SEC. 12. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 4

Veto Message on AB 2308

BILL NUMBER: AB 2308
VETOED DATE: 09/28/2006

To the Members of the California State Assembly:

While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in the se facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner.

Sincerely,

Arnold Schwarzenegger

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes
Tasks:	1. Secure extension of board's sunset date (SB 1476). *Sept. 30, 2006: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.* 2. Sponsor legislation to update pharmacy law (SB 1475). *Sept. 30, 2006: Governor signs SB 1475 containing provisions that:* *(a) Allow a check-off box on electronic prescriptions that if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion (B&P 4073).* *(b) Clarify requirements for reporting to the board when a licensee is impaired to the extent it affects the licensee's safe practice or who has stolen or diverted drugs (B&P 4104).* *(c) Establish the authority to issue a temporary sterile injectable compounding license following a change in ownership (B&P 4127.8)* *(d) Exempt government-owned wholesalers from having to post a $100,000 bond (B&P 4162).* *(e) Exempt drug manufacturers who hold a biologics license application from the FDA from having to post a $100,000 bond otherwise required for nonresident wholesalers (B&P 4162.5).* *(f) Make technical changes in the licensure requirements for clinics (B&P 4180 - 4182, 4190 - 4192).* 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408). *Sept. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.* 4. Secure statutory standards for pharmacies that compound medications (AB 595). *Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

	5. Secure implementation of e-pedigrees on prescription drugs dispensed in California (SB 1476). *Sept. 30, 2006:* *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*
Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). *Aug. 2006:* *Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.* 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). *Aug. 2006:* *Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.* 3. Make technical changes in pharmacy regulations to keep the code updated. Section 1706.2 criteria for abandonment of files Section 1775.4 contested citations Section 1709.1 designation of pharmacist-in-charge Section 1780 standards for wholesalers Section 1780.1 standards for veterinary food animal drug retailers Section 1781 exemption certificate Section 1786 exemptions 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). *July 2006:* *Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.* 5. Revise and update Disciplinary Guidelines revision and update (section 1760). *Aug. 2006:* *Final changes to Disciplinary Guidelines being compiled by staff.* 6. Self-assessment of a wholesaler by the designated representative (section 1784). *July 2006:* *Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.* 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). *Sept. 2006:* *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.* 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. *July 2006:* *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.*

Objective 3.3	Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed
Tasks:	